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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,395	07/05/2006	Włodzimierz Rutynowski	541114-0325045(POL0010-US	1920

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875 15th Street, NW
Washington, DC 20005

EXAMINER

MILES, JONATHAN WADE

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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09/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,395	Applicant(s) RUTYNOWSKI, WLODZIMIERZ	
	Examiner JONATHAN W. MILES	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on * has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Thorne, Jr. et al. (US 6,358,265 B1)** in view of **Czernecki et al. (US 5,356,420)**.

Claim 8: Thorne, Jr. et al. disclose a puncturing device comprising:

a housing (**300**, see figures 19 and 20), wherein a push button (**340**);

a puncturing needle (**90'**) disposed in the housing and at least one side jut (**354**),

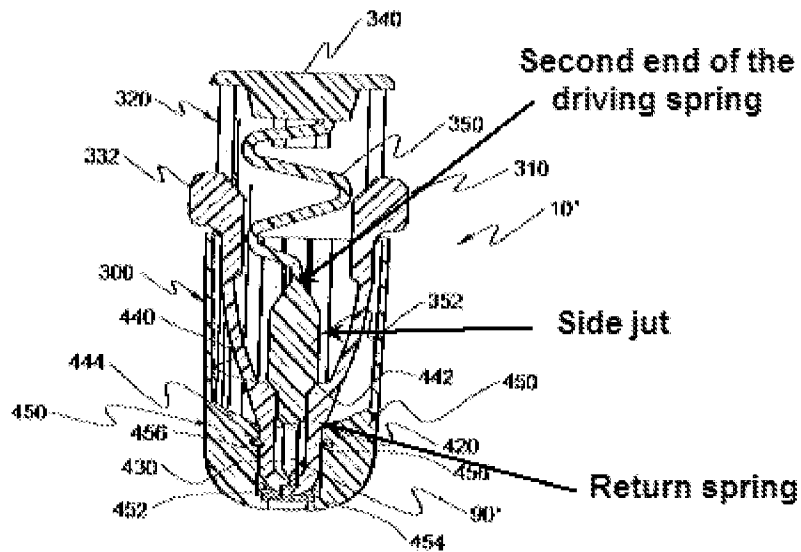
a push button disposed in the housing, wherein the push button has arms (**400**, see figure 22) to guide the push button inside the housing,

one return spring (**420**, where "spring" is taken to be an elastic device) connected to the arms (**400**) of the push button (**340**); and

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a driving spring (**350**) having a first and a second end, wherein the first end is linked to the push button and the second end drives the puncturing needle in a driving direction parallel to a longitudinal axis defined by the puncturing needle,

wherein the side jut (**354**), which is positioned inside the device longitudinally between the return spring and the second end of the driving spring (figures 23 and 17-20, please refer to the figure below)



such that the return spring, side jut, and driving spring are disposed in series along the longitudinal axis before, during, and after use of the puncturing device (figures 17-20, where “series” is taken to mean “arranged one after the other in succession”), and

wherein the return spring acts against the side jut in a direction opposite the driving direction,

but fail to teach the puncturing needle having breakable wings and a corresponding breaking edge in the housing and the needle having a side jut.

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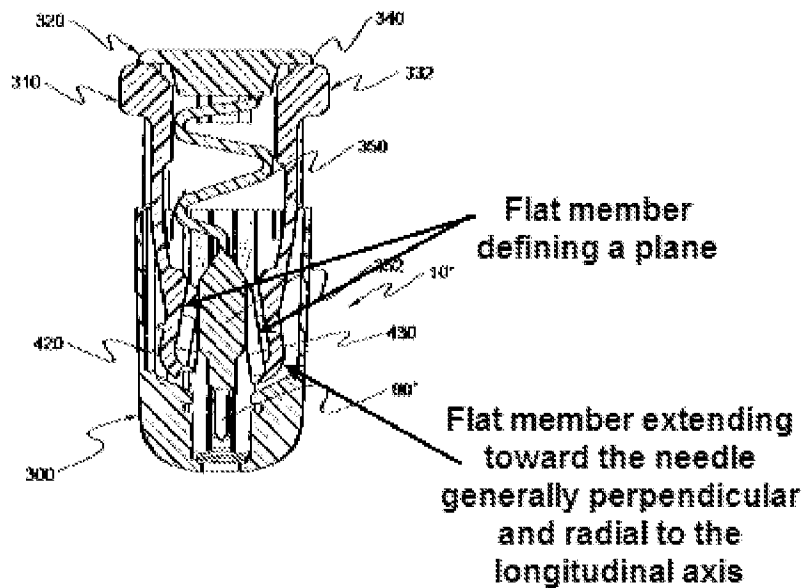
However, Czernecki et al. teach a needle with breakable wings (11) which rest against a breaking edge of the housing (12; please compare figures 1 and 2), as well as a side jut (11).

It would be obvious to one of ordinary skill in the art at the time of the invention to provide the device of Thorne, Jr. et al. with breakable wings as taught by Czernecki, since Czernecki states that such a modification would and ensure that the device is not reused (column 1, lines 59-62) and maintain the tip in a stable position until the push button is activated with a certain force (column 2, lines 29-33 and 35-38).

Claim 9: Thorne, Jr. et al. disclose a device as stated above characterized by two return springs (420, where “spring” is taken to be an elastic device) each of which is connected to one arm (400) of the push button (340), and has two side juts (354), each of which is positioned inside the device between the two return springs (420) and the second end of the driving spring (350).

Claim 10: Thorne, Jr. et al. disclose a device as stated above wherein the return springs (420) are connected approximately perpendicularly to the lower portions of the arms (400) of the push button (340; figure 22), wherein each of the return springs comprises a flat member defining a plane and wherein the flat member extends toward the puncturing needle such that the plane of the flat member is generally perpendicular and radial to the longitudinal axis (please refer to the figure below).

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Claim 11: Thorne, Jr. et al. disclose a device as stated above wherein the first end of the driving spring (350) is connected with the inside face of the push button (340; figures 17-20).

Claim 12: Thorne, Jr. et al. disclose a device as stated above wherein the second end of the driving spring (350) comprises a pusher (352) that pushes the puncturing needle (90').

Claim 13: It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F. 2d 1647 (1987).

Claim 14: Thorne, Jr. et al. disclose a device as stated above wherein the pusher has a cup-shaped end (figure 23) and wherein the puncturing needle fits within the cup-shaped end of the pusher (column 8, lines 35-36), but fails to explicitly state that the needle has a projection that fits within the pusher.

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However, it is obvious to one of ordinary skill in the art at the time of the invention to provide the needle with a projection to fit into the pusher since such a modification would better ensure that the needle does not slip out.

Claim 15: Thorne, Jr. et al. disclose a device as stated above wherein the driving spring (350) is shaped like the letter "S" (figures 17-20).

Claim 16: Thorne, Jr. et al. disclose a device as stated above wherein the return springs (420) are flat springs (figure 22).

Claims 17-18: Thorne, Jr. et al. modified by Czernecki et al. teach a device wherein a first force applied to the push button (*Czernecki et al.*, 2) compresses the driving spring (9) between the push button and the puncturing needle (*Czernecki et al.*, 7) and presses the breakable wings (*Czernecki et al.*, 11) against the breaking edge (*Czernecki et al.*, 12) until said wings break (*Czernecki et al.*, figure 2),

wherein, upon breaking the wings, the driving spring (*Czernecki et al.*, 9) drives the puncturing needles such that a lancet of the puncturing needles extends outside the housing and the side jut (*Czernecki et al.*, 5) contacts the return spring (*Czernecki et al.*, 10, figure 2), and

wherein after the lancet extends outside the housing (*Czernecki et al.*, 1), the return spring (*Czernecki et al.*, 10) applies a second force to the side jut (*Czernecki et al.*, 5) in a direction opposite the first force to pull the lancet of the puncturing needle inside the housing (*Czernecki et al.*, column 2, lines 40-41),

wherein after pulling the lancet of said needle inside the housing (*Czernecki et al.*, 1), the return spring (*Czernecki et al.*, 10) and the driving spring (*Czernecki et al.*, 9) are in a free state (*Czernecki et al.*, column 2, lines 41-42, where a stable position is a free state).

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Claim 19: Thorne, Jr. et al. disclose a device as stated above wherein the arms are integral to the push button (figure 19) before, during, and after use of the puncturing device. It has been held that the term “integral” is sufficiently broad to embrace constructions united by such means as fastening. In re Hotte, 177 USPQ 326, 328 (CCPA 1973).

Claims 20-21: Thorne, Jr. et al. disclose a device as stated above wherein each of the arms of the push button defines a detent to fix the push button in the housing (figure 25 where the arms **400'** fit against beams **460, 462**) and wherein each return spring is connected to the detent of the arm (figure 22),

wherein the puncturing needle has a first end driven by the driving spring and a second end comprising a puncturing portion, wherein the at least one side jut is disposed on the puncturing needle proximate to the first end of the puncturing needle and proximate to the second end of the driving spring (figure of claim rejection 10).

Claim 22: Thorne, Jr. et al. modified by Czernecki et al. teach the device as stated above, but fail to teach the exact arrangement of the side jut and wings relative the needle as claimed.

However, it would be obvious to one of ordinary skill in the art at the time of the invention to adjust the dimensions to achieve the arrangement as claimed since it has been held that rearranging parts of an invention involves only routine skill in the art. in re Japikse, 86 USPQ 70.

Claim 23: Thorne, Jr. et al. disclose a device as stated above wherein the return spring acts against the at least one side jut in a direction generally opposite to the driving direction after a lancet of the puncturing needle extends outside the housing, to pull the lancet in a direction opposite the driving direction along the longitudinal axis and back inside the housing (figure 20,

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where the return spring **420** pushes inwardly on the side jut, acting in a direction perpendicular to the longitudinal axis and thus generally opposite the driving force of the lancet.

Response to Arguments

3. Applicant's arguments with respect to claims 8 and 9 have been considered but are moot in view of the new ground(s) of rejection.

4. For claim 13, figure 18 of Thorne, Jr. et al. is taken to be the pusher contacting the puncturing needle and figure 19 is taken to be the pusher separating from the puncturing needle by becoming more spaced apart. While the pusher does not become discontinuous with the needle, the present limitations of the claim are met. Further detail may add distinction between the teachings of the application and that of the prior art.

5. A less cost-efficient manufacture simply makes for a less likely method of production. It does not necessarily entail that the concept of fashioning a separate pusher and puncturing needle is non-obvious.

6. Regarding claims 17 and 23, the second force acts against the side jut after retraction (figure 20), thus acting in a direction perpendicular to the longitudinal axis. Such a direction is generally opposite the driving force of the lancet.

7. The arms in claim 19 are integral to the push button in that it has been held that the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding. In re Hotte, 177 USPQ 326, 328 (CCPA 1973).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN W. MILES whose telephone number is (571)270-7777. The examiner can normally be reached on Monday-Thursday 7:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JWM

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/14/09